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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. RE38,115 was filed on December 17, 2010, under 35 U.S.C. § 156. Please note that an additional patent term extension application for has been filed for the same NDA, NDA 22-879, for U.S. Patent No. 5,206,248 for the human drug product NUEDEXTA™ (dextromethorphan hydrobromide/quinidine sulfate) which was filed on December 17, 2010, pursuant to the provisions of 37 C.F.R. § 1.785.

The assistance of your Office is requested in confirming that the product identified in the application, NUEDEXTA™ (dextromethorphan hydrobromide/quinidine sulfate), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use. Additionally, please verify that NDA 22-879 was granted permission for commercial marketing or use on October 29, 2010, so that USPTO can determine that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved as required by § 156(d)(1).

It is noted that both dextromethorphan hydrobromide and quinidine sulfate have been previously approved by FDA. New Drug Application (NDA) # 012796 was approved on February 21, 1962 for the drug product Quinidex having as the active ingredient, quinidine sulfate (see attached record for NDA # 012796 from Drugs @ FDA[1]). NDA # 011265 was approved on December 3, 1957 for the drug product Promethazine hydrochloride and destromethorphan hydrobromide having the active ingredients dextromethorphan hydrobromide and quinidine hydrochloride (see attached record for NDA # 011265 from Drugs @ FDA). Additionally, NDA # 019279 was approved on August 24, 1984 for the drug product Dimetane-DX having as active ingredients Brompheniramine maleate, dextromethorphan hydrobromide and pseudoehpedrine hydrochloride (see attached record for NDA # 019279 from Drugs @ FDA). Since each of the active ingreidents in NUEDEXTA has been previously approved by FDA in the NDAs listed above, it does not appear that the permission for the commercial marketing or use of NUEDEXTA meets the requirements of §156(a)(5)(A).

Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

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[1]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Tiff
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Kevin G. Shaw
Hogan Lovells US LLP
555 Thirteenth St., NW
Washington, DC 20004

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# Drug Details

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|---|---|
| **Drug Name(s)** | **QUINIDEX (Brand Name Drug)** |
| **FDA Application No.** | **(NDA) 012796** |
| **Active Ingredient(s)** | **QUINIDINE SULFATE** |
| **Company** | **WYETH PHARMS INC** |
| **Original Approval or Tentative Approval Date** | **February 21, 1962** |
| **Chemical Type** | **3 New formulation** |
| **Review Classification** | **P Priority review drug** |

- **There are no Therapeutic Equivalents**
- **Approval History, Letters, Reviews, and Related Documents**
- **Label Information**

**Products on Application (NDA) #012796**
**Click on a column header to re-sort the table:**

| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | RLD | TE Code |
|---|---|---|---|---|---|---|
| QUINIDEX | QUINIDINE SULFATE | 300MG | TABLET, EXTENDED RELEASE; ORAL | Discontinued | No | None |

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# Drug Details

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|---|---|
| **Drug Name(s)** | **DIMETANE-DX (Brand Name Drug)** |
| **FDA Application No.** | **(NDA) 019279** |
| **Active Ingredient(s)** | **BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE** |
| **Company** | **ROBINS AH** |
| **Original Approval or Tentative Approval Date** | **August 24, 1984** |
| **Chemical Type** | **3 New formulation** |
| **Review Classification** | **S Standard review drug** |

- **There are no Therapeutic Equivalents**
- **Labels are not available**
- **Approval History, Letters, Reviews, and Related Documents**

**Products on Application (NDA) #019279**
**Click on a column header to re-sort the table:**

| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | RLD | TE Code |
|---|---|---|---|---|---|---|
| DIMETANE-DX | BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE | 2MG/5ML; 10MG/5ML; 30MG/5ML | SYRUP; ORAL | Discontinued | No | None |

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# Drug Details

| | |
|---|---|
| **Drug Name(s)** | **PROMETHAZINE HYDROCHLORIDE AND DESTROMETHORPHAN HYDROBROMIDE (Brand Name Drug)** |
| **FDA Application No.** | **(NDA) 011265** |
| **Active Ingredient(s)** | **DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE** |
| **Company** | **ANI PHARMS** |
| **Original Approval or Tentative Approval Date** | **December 3, 1957** |
| **Chemical Type** | **4 New combination** |
| **Review Classification** | **S Standard review drug** |

- **There are no Therapeutic Equivalents**
- **Label Information**
- **Approval History, Letters, Reviews, and Related Documents**

**Products on Application (NDA) #011265**
**Click on a column header to re-sort the table:**

| Drug Name | Active Ingredients | Strength | Dosage Form/Route | Marketing Status | RLD | TE Code |
|---|---|---|---|---|---|---|
| PROMETHAZINE HYDROCHLORIDE AND DESTROMETHORPHAN HYDROBROMIDE | DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE | 15MG/5ML; 6.25MG/5ML | SYRUP; ORAL | Discontinued | No | None |

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